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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,355	11/22/2004	Kenneth Hun Mok	930077-2010	4259

7590 10/16/2006

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,355	MOK, KENNETH HUN	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/20/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pursuant to the response filed 7/20/06 claims 12-15 have been added. Claims 1-15 are now pending.

Applicants' arguments filed 7/20/06 have been considered and found not persuasive.

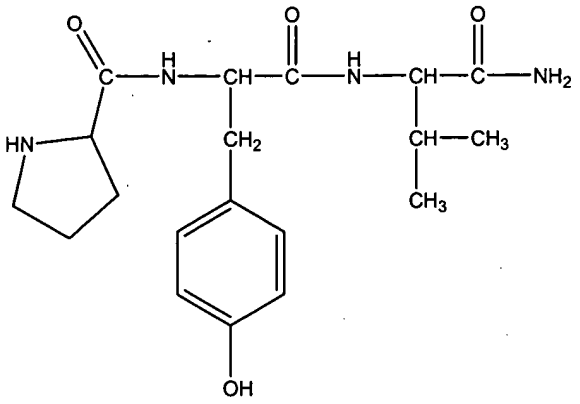
✦

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As noted previously, applicants have provided data (page 6) which shows that certain compounds are effective to mitigate the increase in triglyceride levels that result from administration of olive oil to mice. Based on this data, applicants are asserting that the compounds to which the claims are directed can be used to treat hyperlipidemia (or at least to suppress triglyceride levels). As it happens, however, none of the compounds listed in table 1 falls within the scope of the claimed invention. For example, the peptide originally designated "SEQ ID NO: 2" is the following:



This compound, however, does not fall within the scope of the claims (because of the C-terminal amidation). Nor do any of the other compounds of table 1. Thus, applicants are attempting to extrapolate from one structure to another. The reality in peptide pharmacology is that minor changes in structure often eliminate activity. One cannot "predict" retention of activity when structures are altered.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

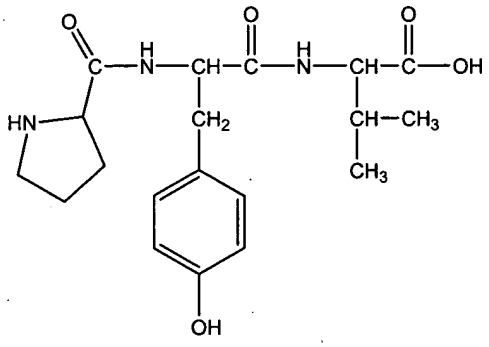
Given the absence of working examples (that show the skilled cardiologist how to use the claimed compounds) and the unpredictability in the art, "undue experimentation" would be required to practice the claimed invention.

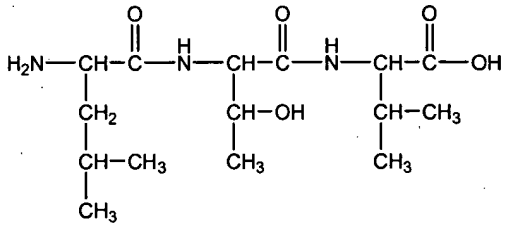
In response to the foregoing, applicants have made essentially four arguments: (a) the EPO determined that the instant claims are novel; (b) a "parallel" application in Europe has been allowed; (c) the instant specification provides adequate guidance as to how the skilled artisan could take a peptide and combine it with a pharmaceutically acceptable carrier; and (d) each of the two peptides referred to in claim 1 is actually a genus of peptides, i.e., the recited sequences are merely subsequences of a larger peptide.

The relevance of applicants' first point (regarding novelty) to the rejection at issue is not apparent, and applicants have made no attempt to explain it. Perhaps the claims will ultimately prove to be novel, and perhaps not; either way, that is an issue which is separate from that of enablement. As for the second point, applicants have preemptively made the examiner's argument by noting that the decision of an examiner in Europe to abstain from imposing an enablement rejection is not binding on the examiner of this application. Thus, decisions made by other examiners in other countries have no bearing on the prosecution of the instant application. As for the third point, the examiner has not argued that

the skilled artisan would be unable to combine a peptide with a pharmaceutically acceptable carrier; accordingly that is a moot issue as well.

Thus, one is left with the issue at hand, which is how to "use" the peptides to which claim 1 is drawn; the peptides at issue are the following:





Applicants have argued that the language of claim 1 is such that what is being claimed is a peptide that comprises Pro-Tyr-Val or Leu-Thr-Val (all "D" amino acids). However, applicants are not correct. There is nothing in the language to signify this. If there is descriptive support for it, applicants could claim the following:

> *A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a peptide, wherein the peptide comprises one of the following two subsequences:*
>
> *D-Pro-D-Tyr-D-Val* *(I)*
> *D-Leu-D-Thr-D-Val* *(II)*

However if descriptive support is lacking for the "comprising" language, applicants will have to accept that the claims are limited to just the two tripeptides referred to above.

And even if there is descriptive support for the "comprising" language, the claims will continue to be rejected because the full scope of the genus would, under the proposed amendment, lack enablement. In particular, the elected peptide lacks enablement. Given that the elected peptide is not allowable, rejection of all the claims under this statute is justified.

✦

Claims ~~1-11~~ 1-15 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 is drawn to a pharmaceutical composition. A "composition", however, must contain at least two compounds (or a compound and another material or substance), otherwise it is a compound. Thus, claim 1 mandates the presence of a second compound, yet provides no clue at to what it might be. Is it a carrier? Is it another peptide? The same issue applies in the case of claim 7.

- Claim 1 is drawn to a pharmaceutical composition "for administration to a human or animal". However, the phrase in quotes appears to be superfluous and can be deleted. For example, if the composition were intended for administration to a plant, the qualifier "pharmaceutical" would be inappropriate. If the composition were to be used in an industrial cleaning fluid, the qualifier "pharmaceutical" would also not be appropriate. Applicants are requested to provide at least one example of an embodiment which they believe is currently encompassed, but which would not be

encompassed if the phrase at issue were to be deleted. Better still would be to simply delete the phrase in question.

- Claim 1 makes reference to a "component". In applicants opinion, how does a "component" differ from a compound? If there is no difference, the term *compound* should be used instead. The same issue applies in the case of claims 12 and 14.

- None of claims 8-11, 13 or 15 is actually subgeneric to claim 1 (or to claim 2, 3, 4, or 5). Claim 1 excludes the possibility that the C-terminal carboxyl group can be replaced with an amino group; claim 1 also excludes the possibility that the N-terminal amino group can be replaced with a carboxyl group. It is suggested that claims 8-11 be cancelled and that a new, independent claim be added which recites a structure (a structure in which contains the requisite malonyl group and a gem-diamino moiety). Particularly puzzling is how applicants intend to replace the "NH_2" group of Pro-Tyr-Val with a carboxyl group, given that proline does not actually have an NH_2 group. Applicants have responded to the foregoing by arguing that the skilled artisan could figure out what applicants intend. The examiner disagrees. In any case, if applicants would like to have help in formulating claim language, applicants may so request. In the event that applicants are unwilling to change the language of the claims, the rejection will be maintained.

✦

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Baumbach (USP 5,831,003) or Nestor (USP 4473555) or Seelig (USP 5451658).

Each of Baumbach, Nestor and Seelig discloses peptides that contain the tripeptide Pro-Tyr-Val as a subsequence (all "L" amino acids). See, e.g., the following:

Baumbach: SEQ ID NO: 6

Nestor: col 8, line 18

Seelig: SEQ ID NO: 4

The references do not disclose replacing all of the "L" amino acids with "D" amino acids.

The first point here is that, according to applicants, the tripeptide Pro-Tyr-Val (all "D" amino acids) in instant claim 1 is merely a subsequence, and not a "stand alone" tripeptide. Applicants' assertion goes a long way towards justifying this ground of rejection. The other issue, of course is that of replacing all of the "L" amino acids with "D" amino acids. However, this is well known in the art. One

motivation for doing this is to increase resistance to protease digestion. If applicants are not familiar with this issue, it is suggested that applicants review the references which are cited in paragraph 0228 (page 21) of US 2005/0049193.

If applicants assertion regarding the scope of claim 1 is correct (and the examiner disagrees with applicants' interpretation), then this ground of rejection is justified.

✦

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON, PH.D.
PRIMARY EXAMINER